

## **CLASSIC** newsletter – June 2020

## Dear friends - the CLASSIC trial is more than halfway

#### **Status**

Since trial start **816 patients** have been randomised by **26 sites in 7 countries.** We reached 50% on May 12<sup>th</sup>, where **Viborg** (Denmark) randomised patient number 777. Well done! ICU **Stavanger** (Norway) has joined the trial. Congratulations and welcome!

ICUs to join in summer 2020:

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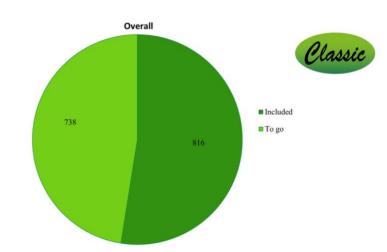
Vall d'Hebron (Spain)

Helsinki, Tampere, Kuopio (Finland)

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Skt Göran (Sweden)

Brno (Czech Republic)



#### **News**

- Because of COVID-19, we have arranged for online meetings with Sponsors center. If your ICU is interested in an initiation or "catch-up" meeting, let us know and we will set it up.
- We have uploaded short videos with presentation of screening and trial interventions:
   <a href="http://www.cric.nu/classic-videos/">http://www.cric.nu/classic-videos/</a> We hope you will find them useful.
- The 3<sup>rd</sup> interim analysis will be conducted by the Data Monitoring and Safety Committee in August 2020 including data on mortality and safety.

# Top recruiters, May 2020



Monthly top-recruiters were **Hillerød** (Denmark) followed by **Aalborg** (Denmark) and **Bern** (Switzerland). Congratulations!



## Important information!

## **Interim analysis**

The 3<sup>rd</sup> interim analysis (50% of patients with 90-day follow-up) will be conducted in August 2020. Please complete data entry for <u>all patients randomised before May 13<sup>th</sup> 2020.</u> All forms must be completed no later than August 10<sup>th</sup> 2020.

#### COVID-19

Patients tested positive for COVID-19 may be included in CLASSIC if they develop septic shock.

### Consent forms in the eCRF

- For Danish sites: all consents and correspondences regarding consent must be uploaded in the eCRF consent module from May 1st 2020 onwards.
- For international sites: currently no international sites use the consent form module. The
  national investigator must contact the CLASSIC coordinating investigator, Tine Meyhoff, if a
  country wants to use the module.

# Meet the CLASSIC investigators

Zealand University Hospital Køge (Denmark) has a 9-bed ICU, admitting patients from emergency department, internal medicine, ENT and surgical patients (mainly gastrointestinal). Køge is the future main specialized hospital for the 837.000 inhabitants in the Zealand region, and in 2024 the capacity will expand to 32 beds. Lone Museaus Poulsen is the Head of the Department, Lars Nebrich is the principal investigator in CLASSIC with great support from the research unit staff (see photo) and the nurses and doctors who all support clinical research in their daily work. Køge ICU is involved in several multicenter trials, and is a part of the Steering Committee of CRIC Sponsoring the AID-ICU trial on delirium <a href="http://www.cric.nu/aid-icu/">http://www.cric.nu/aid-icu/</a>.

Also, Køge will soon have included 100 patients in CLASSIC - congratulations!





Study Team from left to right: Nina Christina Andersen-Ranberg, Lars Nebrich, Camilla Bekker Mortensen, Sidsel Fjordbak Caspersen, Thea Nørgaard Rønsbo, Alison Holten Pind, Camilla Bekker Mortensen (version 2), Lone Musaeus Poulsen

### Contact

You can reach us at <a href="mailto:classic@cric.nu">classic@cric.nu</a> or +45 3545 0606 (available 24/7). For questions related to 1-year follow-up, please contact <a href="mailto:Maj-Brit.Noerregaard.Kjaer@regionh.dk">Maj-Brit.Noerregaard.Kjaer@regionh.dk</a>
Please archive this newsletter in your Site Master File.

Until next time,
Morten, Maj-Brit, Lene, Peter, Anders & Tine

